

Docket No. 371-20-055

PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF APPEALS

In re Application of Helix Medical, Inc.

Filed: April 11, 2001

Art Unit: 3738

Serial No. 09/833,961

Examiner: Thomas C. Barrett

For: MEDICAL DEVICES HAVING ANTIMICROBIAL PROPERTIES

APPELLANT'S BRIEF

Mail Stop Appeal Brief-Patent

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

This is an appeal from the Final Rejection of Claims 17-22

1. *Real Party in Interest.*

The real party in interest is Helix Medical, Inc., the assignee of the instant application

2. *Related Appeals and Interferences.*

None

3. *Status of Claims.*

1. Original

2. Original

3. Original

4. Original

5. Original

6. Original

7. Original
8. Original
9. Original
10. Original
11. Original
12. Original
13. Original
14. Original
15. Original
16. Original
17. Appealed
18. Amended, Appealed
19. Original
20. Amended, Appealed
21. Amended, Appealed
22. Amended, Appealed

The claims on Appeal are elected Claims 17-22.
Claims 1-16 are non-elected.

4. *Status of Amendments.*

No amendments were filed subsequent the Final Rejection

5. *Summary of Invention.*

The invention relates to the discovery that adding antimicrobial materials to the outside surface 215 of the valve 60 at an effective level toxic and irritating to tissue, does not cause irritation of the tissue of the stoma since the stoma is only in fluid contact with the antimicrobial outside surface of the valve. The outside surface of the body 12 of the prosthesis which is in contact with tissue when in use contains a low, non-irritating and non-toxic level of antimicrobial agents. (Page 6, lines 17-26) (Page 9, lines 3-21).

6. *Issues.*

- A. 35 U.S.C. 101 Non-statutory subject matter.
- B. Improper Dependency-Does not further limit subject matter of previous claim
- C. 35 U.S.C. 103(a) Laguette et al in view of Priscott.

7. *Grouping of the Claims.*

- (A) Claims 17-22 stands or falls together
- (B) Claim 18 stands and falls alone
- (C) Claims 17-21 stands and falls alone

8. *Argument.*

5.A. Non-statutory subject matter

Claims 17-22 do not present statutory subject matter.

The preamble to independent Claim 17 states "A voice prosthesis for use in contact with tissue..." The phrase "for use" denotes a future condition. If Applicant intended to claim the combination of a voice prosthesis in a stoma in a human body, he would have stated in Claim 17--A voice prosthesis in contact with tissue--. The preamble is believed to modify the succeeding clauses in the claims and implicitly recites that the body and valve parts of the voice prosthesis will have the stated contact relationships when the voice prosthesis is in use in the body of a subject. Claims 18-22 depend on Claim 17, are subject to the same argument and will stand or fall together with Claim 17.

8.B. Improper Dependency

Claim 18 does further limit Claim 17. Claim 17 states that "outside surface in contact with tissue and containing an antimicrobial agent that is non-irritating and non-toxic to tissue." (Emphasis added)

Claim 18 states that "the outside surface of the wall is non-irritating to and non-toxic to said tissue" (Emphasis

added).

In Claim 17 the outside surface is non-irritating and non-toxic to tissue in general. In Claim 18 the outside surface is non-irritating and non-toxic to the tissue in contact with the outside surface.

8.C. 35 U.S.C. 103(a)

Claims 17-22

The invention is based on a voice prosthesis having an outside surface of a valve which is in intermittent contact with body fluids containing antimicrobial material at a level, which would irritate or be toxic to the tissue in contact with the body of the prosthesis. However, the outside surface of the body that will be in contact with the tissue also contains antimicrobial material but at a different, lower level that is non-irritating and non-toxic to tissue. (Claim 17)

These claims are rejected as being unpatentable over Laguette et al (Page 6, lines 23-26) in view of Priscott (Abstract and Page 7, lines 6-8).

Laguette et al discloses a voice prosthesis formed of a microbial resistant polymer containing a plurality of fluorine atoms pendent from the polymer chain (Page 4, line 19 to Page 5, line 4.)

At Page 6, lines 23-26, Laguette et al states "At least the valve 60 is formed of the yeast resistant material of the invention or contains a thin coating 63 formed on the surface of the valve 60."

At Page 7, lines 25-29, Laguette et al further states that "The microbial resistant surface can be provided by coating or laminating a layer of yeast resistant polymer onto the exposed

surfaces of the valve and body of the prosthesis".

Laguet et al disclose only one antimicrobial material--a fluorinated polymer that is not toxic to tissue (Page 4, line 23). The antimicrobial material utilized on the outside surface of the valve of the invention is toxic to tissue at the level utilized and is not toxic to tissue at the level present in the body of the prosthesis.

The passage at Pages 6 and 7 of Laguet et al indicate that at least the valve or the valve and body can be formed of or coated with a layer of yeast resistant polymer. However, there is no disclosure of use of a material toxic to tissue that is coated onto the valve at one level and the body at another level.

Priscott does not contain any disclosure that would supply the deficiency of the Laguet et al reference.

Priscott's invention relates to the use of Triclosan, a well known antimicrobial used in cosmetics and industrial products, oral care and have disinfectants (Page 5, 5th paragraph). An antimicrobial material is prepared by dispersing Triclosan in a polymer matrix (Page 6, 3rd paragraph) which can control growth of a broad range of microorganisms including fungi, molds, mildew and yeasts on medical devices or prosthesis (Page 2, 3rd paragraph).

The medical devices or prosthesis would contain an even amount of Triclosan over the complete interior and exterior surface of a device according to Priscott. There is no disclosure of selective application of the Triclosan containing polymer to the valve of a voice prosthesis at one level and the body at another level.

Claim 22.

The specific disclosure of the use of 0.2 to 5% weight of butyl paraben or Triclosan or to 50phr of silver oxide in a voice prosthesis containing different levels of the antimicrobial in the valve and body are believed to be patentable for the reason stated above and for the separate reason that since Laguette et al does not teach the use of antimicrobial surfaces at different levels the combination with Priscott would result in the same microbial loading of Triclosan on all surfaces. Therefore, one skilled in the art would only combineLaguette et al with Priscott after a reading of the present disclosure for the use of Triclosan at a specific level.

8.D. *Parties*

There are no other parties to this appeal.

9. *Appendix.*

17. A voice prosthesis for use in contact with tissue comprising in combination:

a tubular body having a central channel and an annular wall having an inside surface not in contact with tissue and an outside surface in contact with tissue and containing antimicrobial material at a level that is non-irritating and non-toxic to tissue;

5 a valve having an inside surface and an outside surface and being mounted to seal and intermittently open said channel, said outside surface of the valve being in contact with body fluids; and

10 the outside surface of the valve not being in direct contact with tissue and having antimicrobial properties at a level that would irritate or be toxic to that tissue.

18. A voice prosthesis according to claim 17 in which the outside surface of the wall is in contact with tissue and the outside surface of the wall is non-irritating to and non-toxic to said tissue.

19. A voice prosthesis according to claim 18 in which said body and said valve are formed of an elastomer.

20. A voice prosthesis according to claim 19 in which the valve is formed of a silicone elastomer containing a dispersion or outside coating of an antimicrobial material.

21. A voice prosthesis according to claim 20 in which the antimicrobial material is selected from metal salts, metal oxides and organic antimicrobial materials.

22. A voice prosthesis according to claim 21 in which the material is selected from silver oxide in an amount from 6 to at least 50 phr and butyl paraben or triclosan in an amount from 0.2 to 5% by weight dispersed in the resin forming the valve.

Conclusion

For the above reasons its is believed that the Examiner is in error as to all grounds of rejection and reversal is believed to be in order and is respectfully solicited.

Respectfully submitted,



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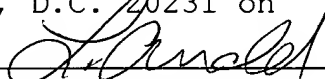
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